JUN 2 6 2001

K003927

CHEEN HOUNG ENTERPRISE CO., LTD

23, ALLEY 11, LANE 65, SAN DREEN STREET, SHULIN (23805) TAIPEI SHENG TAIWAN R.O.C
TEL : 886-2-2689-2001 FAX : 886-2-2689-2468
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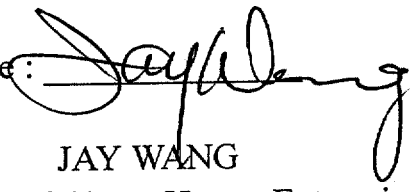
SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The Cheen Houng Enterprise Co., Ltd. Y2000 Manual Resuscitator Units are similar in intended use, design, material selection, performance and function to Life Support Products (Allied Healthcare Products) Resuscitator which are currently legally and safety marketed in the United State. No new technological characteristics that could affect safety or effectiveness have been introduced.

Therefore, it is our conclusion that the Cheen Houng Enterprise Co., Ltd. Y2000 Manual Resuscitator Units are safe and effective for their intended function.

Signature : 

Date : APR 30th, 2001

JAY WANG
President of Cheen Houng Enterprise Co., Ltd.

MALAYSIA PLANT: PLAXTRON INDUSTRIAL (M) SDN. BHD.
Plot 28, Free Trade Zone, Jelapang II, 30020 Ipoh, Perak, Malaysia

CHINA PLANT: POLYMED (XIAMEN) PLASTIC INDUSTRIAL CO., LTD
Unit B, 1~5 F, Warehouse & Process Complex Building Xiangyu F. T. Z., Xiamen, China
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Jay Wang
Cheen Houng Enterprise Co., Ltd.
23, Alley 11, Lane 65, San Dreen Street
Shulin (23805) TAIPEI SHENG
TAIWAN R.O.C.

Re: K003927
(I) Cheen Houng General Use Resuscitator, Model REGU01 & RUGU02
(II) Cheen Houng Golden Hygeia Resuscitator, Model RUGH01 & RUGH02
Regulation Number: 868.5915
Regulatory Class: II (two)
Product Code: BTM
Dated: April 30, 2001
Received: May 3, 2001

Dear Mr. Brennan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003927

INDICATION FOR USE

The Cheen Houng Y2000 MANUAL RESUSCITATOR are device incorporating a bag and valve, intended to provide emergency ventilation or ventilation during patient transport. The infant model is intended for patients from 5 to 12 kgs, the child model is intended for patient from 10 to 20 kgs, and the adult model is intended for patient larger than 20 kgs approximate weight. The reusable ventilator models (silicone bag or HTPR bag) are intended for reprocessing, the disposable models (latex bag or PVC bag) are not intended for reprocessing.

Division of Cardiovascular & Respiratory Devices
510(k) Number K003927

Prescription Use Only